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110TH CONGRESS
2D SESSION

H. R. 5605

To amend title XI of the Social Security Act to provide for transparency in the relationship between physicians and manufacturers of drugs, devices, or medical supplies for which payment is made under Medicare, Medicaid, or SCHIP, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 13, 2008

Mr. DEFazio (for himself, Mr. STARK, Mr. BERRY, Mr. CHANDLER, Mr. MORAN of Virginia, Mr. HINCHEY, Mr. MCGOVERN, Mr. ISRAEL, Mr. DOGGETT, Ms. LEE, Mr. WU, and Mr. KUCINICH) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XI of the Social Security Act to provide for transparency in the relationship between physicians and manufacturers of drugs, devices, or medical supplies for which payment is made under Medicare, Medicaid, or SCHIP, and for other purposes.

- 1 *Be it enacted by the Senate and House of Representa-*
- 2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Physician Payments
3 Sunshine Act of 2008”.

4 **SEC. 2. QUARTERLY TRANSPARENCY REPORTS FROM MAN-**
5 **UFACTURERS OF COVERED DRUGS, DEVICES,**
6 **OR MEDICAL SUPPLIES UNDER MEDICARE,**
7 **MEDICAID, OR SCHIP.**

8 Part A of title XI of the Social Security Act (42
9 U.S.C. 1301 et seq.) is amended by inserting after section
10 1128F the following new section:

11 **“SEC. 1128G. QUARTERLY TRANSPARENCY REPORTS FROM**
12 **MANUFACTURERS OF COVERED DRUGS, DE-**
13 **VICES, OR MEDICAL SUPPLIES UNDER MEDI-**
14 **CARE, MEDICAID, OR SCHIP.**

15 “(a) REPORTING OF PAYMENTS OR OTHER TRANS-
16 FER OF VALUE.—On January 1, 2009, and the first day
17 of each fiscal year quarter beginning thereafter, each man-
18 ufacturer of a covered drug, device, or medical supply who
19 provides a payment or other transfer of value, directly,
20 indirectly, or through an agent, subsidiary, or other third
21 party, to a physician; to an entity that a physician is em-
22 ployed by, has tenure with, or has a significant ownership
23 interest in; or to a covered organization in which a physi-
24 cian has a significant professional membership interest,
25 shall submit to the Secretary, in such electronic form as
26 the Secretary shall require, the following:

1 “(1) The name of—

2 “(A) the physician;

3 “(B) if a payment or other transfer of
4 value was provided to an entity that the physi-
5 cian is employed by, has tenure with, or has a
6 significant ownership interest in, the name of
7 the entity; and

8 “(C) if a payment or other transfer of
9 value was provided to an organization so speci-
10 fied in which the physician has such a signifi-
11 cant professional membership interest, the
12 name of the organization.

13 “(2) The address of—

14 “(A) the physician’s office;

15 “(B) in the case of an entity required to
16 be named under paragraph (1)(B), the primary
17 place of business or headquarters for the entity;
18 and

19 “(C) in the case of an organization re-
20 quired to be named under paragraph (1)(C),
21 the primary place of business or headquarters
22 of the organization.

23 “(3) The facility with which the physician is af-
24 filiated, if any.

1 “(4) The value of the payment or other transfer
2 of value.

3 “(5) The date on which the payment or other
4 transfer of value was provided.

5 “(6) A description of the nature of the payment
6 or other transfer of value, indicated (as appropriate
7 for all that apply) as—

8 “(A) compensation;

9 “(B) food, entertainment, or gifts;

10 “(C) trips or travel;

11 “(D) a product or other item provided for
12 less than market value;

13 “(E) participation in a medical conference,
14 continuing medical education, other educational
15 or informational program or seminar, or funded
16 research (such as lab-based, epidemiology, or
17 health services research) that is not a clinical
18 trial; provision of materials related to such a
19 conference, educational or informational pro-
20 gram or seminar, or research; or remuneration
21 for promoting or participating in such a con-
22 ference, educational or informational program
23 or seminar, or research;

24 “(F) product rebates or discounts;

25 “(G) consulting fees or honoraria;

1 “(H) dividend, profit distribution, stock or
2 stock option grant, or any ownership or invest-
3 ment interest held by a physician in a manufac-
4 turer (excluding a dividend or other profit dis-
5 tribution from, or ownership or investment in-
6 terest in, a publicly traded security and mutual
7 fund (as described in section 1877(c)); or

8 “(I) any other economic benefit, as defined
9 by the Secretary.

10 “(7) The purpose of the expenditure according
11 to categories specified by the Secretary, such as con-
12 sulting, education, royalty, and research.

13 “(b) ANNUAL SUMMARY REPORT.—Each manufac-
14 turer of a covered drug, device, or medical supply that is
15 required to submit information under subsection (a) dur-
16 ing a year shall submit a report to the Secretary not later
17 than December 31 of the year that summarizes, in such
18 electronic form as the Secretary shall specify, each submis-
19 sion of information under subsection (a) made by the man-
20 ufacturer during the year. The summary report shall in-
21 clude the aggregate amount of all transfers of anything
22 of value that is less than \$25, including any compensation,
23 gift, honorarium, speaking fee, consulting fee, travel, dis-
24 count, cash rebate, or services.

1 “(c) REPORTING DATE FOR APPLICABLE CLINICAL
2 TRIALS.—

3 “(1) IN GENERAL.—Notwithstanding subsection
4 (a), a payment or other transfer of value made for
5 the general funding of a clinical trial described in
6 paragraph (2) shall be disclosed in the first quar-
7 terly report after the date clinical trial information
8 for such trial is required to be posted under section
9 402(j)(2)(D) of the Public Health Service Act.

10 “(2) CLINICAL TRIAL.—A clinical trial de-
11 scribed in this paragraph is an applicable clinical
12 trial for which clinical trial information is required
13 to be submitted under section 402(j)(2)(C) of the
14 Public Health Service Act.

15 “(d) PENALTY FOR NONCOMPLIANCE.—Any manu-
16 facturer of a covered drug, device, or medical supply that
17 knowingly fails to submit information required under sub-
18 section (a) or (b) in accordance with regulations promul-
19 gated to carry out such subsection, shall be subject to a
20 civil money penalty of not less than \$10,000, but not more
21 than \$100,000, for each such failure. Such penalty shall
22 be imposed and collected in the same manner as civil
23 money penalties under subsection (a) of section 1128A are
24 imposed and collected under that section.

1 “(e) PUBLIC AVAILABILITY.—Not later than June 1,
2 2009, the Secretary shall establish procedures to ensure
3 that the information reported under subsection (a) and the
4 summary reports submitted under subsection (b) are read-
5 ily accessible to the public through an Internet website
6 that is easily searchable, downloadable, and understand-
7 able.

8 “(f) REPORT TO CONGRESS.—Not later than April
9 1 of each year beginning with 2010, the Secretary shall
10 submit to Congress a report that includes the following:

11 “(1) The information submitted under sub-
12 sections (a) and (b) during the preceding year, ag-
13 gregated for each manufacturer of a covered drug,
14 device, or medical supply that submitted such infor-
15 mation during such year.

16 “(2) A description of any enforcement actions
17 taken to carry out this section, including any pen-
18 alties imposed under subsection (d), during the pre-
19 ceding year.

20 “(g) DEFINITIONS.—In this section:

21 “(1) COVERED DRUG, DEVICE, OR MEDICAL
22 SUPPLY.—The term ‘covered drug, device, or med-
23 ical supply’ means any drug, biological product, de-
24 vice, or medical supply for which payment is avail-

1 able under title XVIII or a State plan under title
2 XIX or XXI (or a waiver of such a plan).

3 “(2) COVERED ORGANIZATION.—The term ‘cov-
4 ered organization’ means an organization that is in-
5 volved in health care financing, organization, or de-
6 livery.

7 “(3) MANUFACTURER OF A COVERED DRUG,
8 DEVICE, OR MEDICAL SUPPLY.—The term ‘manufac-
9 turer of a covered drug, device, or medical supply’
10 means any entity—

11 “(A) with annual gross revenues that ex-
12 ceed \$1,000,000; and

13 “(B) which is engaged in the production,
14 preparation, propagation, compounding, conver-
15 sion, or processing of a covered drug, device, or
16 medical supply.

17 “(4) PAYMENT OR OTHER TRANSFER OF
18 VALUE.—

19 “(A) IN GENERAL.—The term ‘payment or
20 other transfer of value’ means a transfer of
21 anything of value that exceeds \$25, and in-
22 cludes any compensation, gift, honorarium,
23 speaking fee, consulting fee, travel, discount,
24 cash rebate, services, or dividend, profit dis-
25 tribution, stock or stock option grant, or any

ownership or investment interest held by a physician in a manufacturer (excluding a dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund (as described in section 1877(c)).

“(B) EXCLUSIONS.—Such term does not include the following:

“(i) Product samples that are intended for patients.

“(ii) A payment or other transfer of value made for the general funding of a clinical trial, other than an applicable clinical trial for which clinical trial information is required to be submitted under section 402(j)(2)(C) of the Public Health Service Act.

“(iii) A transfer of anything of value to a physician when the physician is a patient and not acting in his or her professional capacity.

“(iv) Compensation paid by a manufacturer of a covered drug, device, or medical supply to a physician who is directly

1 employed by and works solely for such
2 manufacturer.

3 “(5) PHYSICIAN.—The term ‘physician’ has the
4 meaning given that term in section 1861(r).

5 “(6) SIGNIFICANT PROFESSIONAL MEMBERSHIP
6 INTEREST.—The term ‘significant professional mem-
7 bership interest’ means, with respect to a physician
8 and a covered organization, the physician is a vol-
9 untary paying member of such organization or the
10 physician receives professional certification through
11 such organization.”.

12 **SEC. 3. LIMITATION ON TAX DEDUCTIONS FOR ADVER-**
13 **TISING BY CERTAIN MANUFACTURERS OF**
14 **DRUGS, DEVICES, OR MEDICAL SUPPLIES.**

15 (a) IN GENERAL.—Part IX of subchapter B of chap-
16 ter 1 of subtitle A of the Internal Revenue Code of 1986
17 (relating to items not deductible) is amended by adding
18 at the end the following:

19 **“SEC. 280L. LIMITATION ON TAX DEDUCTIONS FOR ADVER-**
20 **TISING BY CERTAIN MANUFACTURERS OF**
21 **DRUGS, DEVICES, OR MEDICAL SUPPLIES.**

22 “(a) IN GENERAL.—No deduction shall be allowed
23 under this chapter for any taxable year for any expendi-
24 ture relating to the advertising, promoting, or marketing
25 (in any medium) of any covered drug, device, or medical

1 supply manufactured by the taxpayer if, during the tax-
2 able year, a penalty is imposed on the taxpayer under sec-
3 tion 1128G(d) of the Social Security Act (relating to quar-
4 terly transparency reports from manufacturers of covered
5 drugs, devices, or medical supplies under Medicare, Med-
6 icaid, or SCHIP).

7 “(b) DEFINITIONS AND SPECIAL RULES.—For pur-
8 poses of this section—

9 “(1) COVERED DRUG, DEVICE, OR MEDICAL
10 SUPPLY.—The term ‘Covered drug, device, or med-
11 ical supply’ has the meaning given such term by sec-
12 tion 1128G(g) of the Social Security Act.

13 “(2) AGGREGATION RULES.—All members of
14 the same controlled group of corporations (within
15 the meaning of section 52(a)) and all persons under
16 common control (within the meaning of section
17 52(b)) shall be treated as 1 person.”.

18 (b) CONFORMING AMENDMENT.—The table of sec-
19 tions for such part IX is amended by adding after the
20 item relating to section 280H the following:

“Sec. 280I. Limitation on tax deductions for advertising by certain manufactur-
ers of drugs, devices, or medical supplies.”.

21 (c) EFFECTIVE DATE.—The amendments made by
22 this section shall apply to taxable years beginning ending
23 after the date of the enactment of this Act.

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